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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,555	09/25/2000	Veronique M. Braud	SHP-PT059	9366

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EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,555	BRAUD ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-34,36,37,46,47 and 49-54* is/are pending in the application.

4a) Of the above claim(s) *54* is/are withdrawn from consideration.

5)☒ Claim(s) *32-34,36,37,46 and 50-53* is/are allowed.

6)☒ Claim(s) *47 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/GB98/03686.

Claims 1-31, 35, 38-45 and 48 have been canceled.

New claim 54 has been added.

Claims 32-34, 36, 37, 46, 47 and 49-54 are currently pending

Election/Restrictions

1. Newly submitted claim 54 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 54 is a reach-through claim drawn to a method of treatment using "identified compounds." Therapeutic administration of compounds is distinct from methods of identifying compounds and diagnostic methods previously under consideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 54 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. **In view of Applicant's amendment and remarks filed February 10, 2006 only the following grounds of rejection are maintained.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 47 and 49 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It was previously stated: "Claims 47 and 49 are dependent claims each reciting a method "using the identified compounds in medical diagnostic procedures." These are reach-through claims and lack adequate written descriptive support of the claimed compounds and their use in the claimed procedures.

Base claims 32 and 46 each recite a method for identifying compounds that affect HLA-E binding to CD94, but the specification does not disclose the compounds identified by the method. The claimed

method of medical diagnostic procedures thus cannot be practiced based upon the instant specification, even considering the knowledge of one skilled in the art. No compounds that will perform the claimed medical diagnostic procedures are disclosed, nor has any evidence been shown that such a compound was known. The specification describes assays for screening compounds and even what can be done with any compounds that may potentially be identified through those assays, including medical diagnostic procedures. However, the specification does not disclose just which compounds have the desired characteristic of affecting HLA-E binding to CD94. Without such disclosure, the claimed method cannot be said to have been described. (See Univ. Rochester v... (CAFC, 2004) 69USPQ2d 1886)

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111) clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, ((CAFC, 1991) 18 USPQ2d 1016)."

Applicant's arguments filed February 10, 2006 have been fully considered but they are not persuasive.

The reach-through claims 47 and 49 have been amended to recite that the "identified compounds are antibodies." Applicant asserts that the claims as amended are fully supported in the specification. The Examiner respectfully disagrees. The alleged support in the specification discloses the use of antibodies with known anti-CD94 or known anti-NKG2 binding properties to show that CD94/NKG2 is the binding target of HLA-E by inhibiting HLA-E staining of CD94/NKG2-positive cells. Said disclosure does not describe the use of the inhibition of binding HLA-E to CD94/NKG2 to identify compounds, including antibodies, that inhibit the binding or biological activity. There is no disclosure that these antibodies used to demonstrate that HLA-E binds to CD98/NGK2 is then further used for "medical diagnostic procedures." Applicant is reminded that obviousness is not the standard for the addition new limitations to the disclosure as filed. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). Furthermore, the only antibodies disclosed in the example are anti-CD94 and anti-NGK2A/B antibodies. There is no description of antibodies that bind to any other determinant that may inhibit the HLA-E binding.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 50 stands rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step for producing any compound. The claim is drawn to a method of producing a compound that affects the binding of HLA-E to CD94/NKG2 receptors. However, the claim recites only steps for selecting a test compound, incubating the test compound with cells and determining whether the compound affects binding. There is no provision for a step to "produce" the compound.

Applicant has amended the claim to recite "whereby the test compounds which affect the binding of HLA-E to the cells are the identified compounds." However, this is merely a further recitation of what the compound is, not a step for producing the compound. Accordingly, the omission amounting to a gap between the steps of the claim remains.

Conclusion

5. Claims 32-34, 36, 37, 46 and 50-53 are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
May 15, 2006

David a Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182